



Package leaflet: Information for the user
STRONG PHOLCODINE LINCTUS BP
Pholcodine BP 10 mg/5 ml

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist or nurse have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

What is in this leaflet:

1. What Strong Pholcodine Linctus is and what it is used for
2. What you need to know before you take Strong Pholcodine Linctus
3. How to take Strong Pholcodine Linctus
4. Possible side effects
5. How to store Strong Pholcodine Linctus
6. Contents of the pack and other information

1. What Strong Pholcodine Linctus is and what it is used for

Strong Pholcodine Linctus 10 mg/5 ml is a medicine which helps you to stop coughing, especially if you have a dry non-productive cough. It is related to morphine and codeine, and it acts to stop your automatic cough response.

2. What you need to know before you take Strong Pholcodine Linctus

Because colds are caused by viruses, not bacteria, antibiotics don't help. Here are simple steps to help you when you have a cough or cold.

1. **If you are hot/feverish:** Increase the amount of fluid you normally drink. Lower your temperature with a paracetamol or ibuprofen medicine.
2. **For coughs:** Coughing serves a purpose, it helps clear phlegm and mucus, drink plenty of warm clear fluids.
3. **To help with breathing:** Plain saline nose drops/sprays can help with blocked noses.

Do not take Strong Pholcodine Linctus if you have:

- an allergy (hypersensitivity) to pholcodine or any of the other ingredients of Strong Pholcodine Linctus (see Section 6 and end of Section 2).
- liver disease.
- breathing problems, asthma, bronchitis or bronchiectasis (a lung disorder).
- ever developed a severe skin rash or skin that peels, blisters and/or sores in the mouth after taking pholcodine.

This medicine is not recommended for use in children.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Strong Pholcodine Linctus.

Consult a doctor before use if you have a history of drug abuse; pholcodine is an opioid and addiction is observed with opioids as a class.

Cases of cross-reactivity with medicines called muscle relaxants used during anaesthesia, resulting in serious allergic reactions (anaphylaxis) have been reported in patients who have previously taken pholcodine. If you are due to undergo anaesthesia at any time (such as for surgery), please inform your anaesthetist that you have taken pholcodine in the past.

Take special care with Strong Pholcodine Linctus and talk to your doctor or pharmacist if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Serious skin reactions, including acute generalized exanthematous pustulosis (AGEP), have been reported with the use of pholcodine. AGEP is a generalized, red, scaly rash with bumps under the skin and vesicles associated with fever. Most common location: mainly located on the folds of the skin, the trunk and the upper limbs. The highest risk of serious skin reactions occurrence is especially during the first week of treatment. If you develop a severe rash or any of these skin symptoms, stop taking this medicine and contact or see a doctor immediately.

Other medicines and Strong Pholcodine Linctus

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines especially the following:

- anti-depressants known as monoamine-oxidase inhibitors (MAOIs or tricyclics) or medicines for mood disorders (e.g. phenothiazines). Pholcodine should NOT be taken at the same time as or within 14 days of stopping MAOIs.

You must not consume alcohol while taking this medicine as this may increase drowsiness.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Strong Pholcodine Linctus should **not** be taken unless considered essential by your doctor.

Driving and using machines

Strong Pholcodine Linctus may cause drowsiness. Do not drive or operate machinery until you know how the medicine will affect you.

Important information about some of the ingredients of Strong Pholcodine Linctus

Strong Pholcodine Linctus contains:

- **Liquid maltitol:** if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- **Ethanol:** This medicine contains less than 59.21 mg of alcohol (ethanol) in each 5 ml which is equivalent to 1.464% v/v. The amount in 5 ml of this medicine is equivalent to less than 1.5 ml beer or 1 ml wine. The amount of alcohol in this medicine is not likely to have an effect in adults and adolescents, and its effects in children are not likely to be noticeable. It may have some effects in younger children, for example feeling sleepy. The alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines. If you are pregnant or breast-feeding, talk to your doctor or pharmacist before taking this medicine. If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine.
- **Sodium benzoate:** this medicine contains 6 mg benzoate salt in each 5 ml spoonful which is equivalent to 1.2 mg/ml.
- **Sodium:** this medicine contains less than 1 mmol sodium (23 mg) per 5 ml spoonful, that is to say essentially 'sodium-free'.

3. How to take Strong Pholcodine Linctus

Always take the product exactly as advised. You should check with your doctor or pharmacist if you are not sure. Only to be taken by mouth.

The usual dose is:

Adults:	One 5 ml spoonful 3 - 4 times in any 24 hours.
Children:	Not recommended.

Warning: Do not take more medicine than the label tells you to.

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**If you take more Strong Pholcodine Linctus than you should**

If you or someone else takes too much Strong Pholcodine Linctus, you should contact your doctor or pharmacist who will recommend what action you should take.

If you forget to take Strong Pholcodine Linctus

If you miss a dose, take it as soon as you remember and take any remaining doses for that day at evenly spaced times. **Do not** take a double dose to make up for the forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

STOP using Strong Pholcodine Linctus and seek advice from your doctor if you experience a rare allergic reaction, including skin rashes, swollen face, lips, tongue, difficulty breathing, increased sensitivity to light, inflammation of the blood vessels, fever or shock.

You may also notice the following more common side effects:

- nausea, constipation
- drowsiness

Not known: frequency cannot be estimated from the available data

Generalized rash, red and scaly with bumps under the skin and vesicles associated with fever at the beginning of treatment (generalized acute exanthematous pustulosis). If you develop these symptoms stop using this medicine and contact or see a doctor immediately.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Strong Pholcodine Linctus

Keep out of the sight and reach of children.

Do not use Strong Pholcodine Linctus after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original container to protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information**What Strong Pholcodine Linctus contains:**

- The **active substance** is Pholcodine BP 10 mg/5 ml.
- The **other ingredients** are citric acid monohydrate, sodium carboxymethylcellulose, glycerol, sodium benzoate (E211), saccharin sodium, hydrogenated glucose syrup (E965), ethanol, raspberry/cola flavour and purified water. See end of Section 2.

What Strong Pholcodine Linctus looks like and contents of the pack

Strong Pholcodine Linctus is a clear colourless solution, available in 2000 ml, 1000 ml or 500 ml plastic (HDPE) bottles. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.

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